UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/171,740	04/20/99	IGNATIOUS	F 10391/003001

HM12/0606

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EXAMINER	
WARE, T	
ART UNIT	**PAPER NUMBER**
1615	8

DATE MAILED: 06/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/171,740	Ignatious Et At
Examiner	**Group Art Unit**
Todd D. Ware	1615

☒ Responsive to communication(s) filed on *Mar 20, 1900*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-21, 40, and 65* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21, 40, and 65* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Receipt of request for extension of time (granted) and response to restriction requirement both filed 3-20-00 is acknowledged.

Applicant's election with traverse of Group I, claims 1-21, 40, and 65, and the species somatostatin in Paper No. 7, filed March 20, 2000 is acknowledged. The traversal is on the ground(s) that the examiner has erred in the interpretation of unity of invention under the standard of a single inventive concept; that the IPEA issued a search report and an examination report based on all of the claims presented in the PCT; and that each of the groups of inventions have the special technical feature. This is not found persuasive because the applicant has not presented any scientific evidence nor stated on the record that the inventions are unpatentable over each other, based on, for example, the examiner finding a 35 USC 102(b) reference for Group I, said reference rendering the remaining groups obvious. Rule 13.2, circumstances in which the requirement of unity of invention is to be considered fulfilled, permits the examiner to restrict when there are additional technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Applicant has not stated on the record that the additional ingredients, process steps and procedures, fail to contribute over the art. It is the position of the examiner that in US practice all claim limitations are to be given weight in making a comparison with the art. Steps such as mixing, obtaining, dissolving, isolating, centrifuging or filtering each represent significant limitations that are capable of supporting a separate patent within the art. It would be contrary to US practice to find persuasive, arguments

directed to a single feature, presented among many, that all claims have a related feature. To assume this position would render restriction practice moot. Rarely do applicants present claims directed to clearly distinct inventions such as a carburetor and a pharmaceutical agent. Applications usually present related inventions and under 35 USC 101 applicants are entitled to obtain a patent to a single invention. Finally, it is noted that the search report and International Examination Report was based on as search conducted in Ireland and did not involve the US as the searching authority or be subjected to US rules of examination, including classifications of inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-21, 40 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5, and 8 fail to us Markush language and are unclear as to what is claimed (see MPEP 2173.05 (h). In lines 7-8 of claim 1, the solution is said to comprise acetone, acetonitrile, ethyl acetate, tetrahydrofuran, or glyme. Is acetone, acetonitrile, ethyl acetate, tetrahydrofuran one group and glyme a second or is each compound one species? The specification provides

support for each compound as a separate species and it is unclear whether two groups or five species are being claimed. The examiner suggests amending the claim to include "selected from the group consisting of" language to further distinguish the species. The same situation occurs in claims 5 and 8. Correction is requested.

3. Claim 21 recites the limitation "vacuum drying" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-10, 12-21, 40 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Shalaby et al (WO 94/15587; hereafter '587).

'587 discloses peptide-polymer ionic conjugate microparticles wherein the polymer is a polyester that is the same as the instant invention (paragraph bridging pages 4 and 5, paragraph bridging pages 6 and 7, Tables 1-3, 6, Example 11). The disclosed peptide is either LHRH or somatostatin. Example 11 of '587 discloses the instant methods. Ionic conjugates are formed by dissolving a biodegradable polymer in a liquid, while a peptide (drug) is dissolved in another liquid. These liquids are essentially mixed to form the peptide-polymer ionic conjugate and added to acetone. In the paragraph bridging pages 4 and 5 and the paragraph bridging pages 6 and 7,

'587 discloses that tetrahydrofuran (THF) or acetonitrile, or mixtures thereof is substituted for or with acetone. The acetone/peptide-polymer solution is then injected into water or alcohol (page 19, lines 1-16) in small droplets. The polymer/peptide complex then separates immediately into small particles which are then subjected to reduced pressure to remove residual acetone and centrifuged.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-21, 40 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al (WO 94/15587; hereafter '587).

'587 teaches peptide-polymer ionic conjugate microparticles wherein the polymer is a polyester that is the same as the instant invention (paragraph bridging pages 4 and 5, paragraph bridging pages 6 and 7, Tables 1-3, 6, Example 11). The disclosed peptide is either LHRH or somatostatin. Example 11 of '587 teaches the instant methods. Ionic conjugates are formed by dissolving a biodegradable polymer in a liquid, while a peptide (drug) is dissolved in another liquid. These liquids are essentially mixed to form the peptide-polymer ionic conjugate and added to acetone. In the paragraph bridging pages 4 and 5 and the paragraph bridging pages 6 and 7, '587 discloses that tetrahydrofuran (THF) or acetonitrile, or mixtures thereof is substituted for or

with acetone. The acetone/peptide-polymer solution is then injected into water or alcohol (page 19, lines 1-16) in small droplets. The polymer/peptide complex then separates immediately into small particles which are then subjected to reduced pressure to remove residual acetone and centrifuged. '587 is silent as to the limitations of the instant claim 11, where the alcohol is maintained between about 0 C to about -30 C or 0 C and -70 C. However, since the process of '587 is otherwise the same as the instant claims and results in the formation of microparticles, the temperature limitations of the instant claim 11 are not afforded patentable weight absence a demonstration of criticality thereto. Furthermore, it would be within the gambit of one skilled in the art to form the microparticles at a temperature that allowed for the quickest, most easily formed, or desirable microparticles.

8. Claims 1-21, 40 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shalaby et al (WO 94/15587; hereafter '587) in view of Khan et al (WO 93/17668; hereafter '668).

'587 is relied upon for all that it teaches as stated above.

'668 is relied upon for teaching formation of microparticles using a frozen non-solvent such as ethanol (paragraph bridging pages 8 and 9) to extract the solvent for the polymer as the frozen microspheres thaw.

Accordingly, it would be obvious to one skilled in the art at the time of the invention to maintain the non-solvent alcohol (first liquid wherein conjugate is not soluble) of the step in '587 where the acetone/peptide-polymer solution is injected into alcohol at a temperature that is below

the freezing temperature of the polymer/active agent solution with the expectation that doing so would allow for extraction of the solvent and a motivation being a desire to remove the solvent from the microspheres.

Conclusion

9. Currently, no claim is allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on Monday through Friday from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235 or 308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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